DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-27

April 9, 2004

Sebastien (NMI) Francois, President
Sebastien and Marie Seafood Inc.
1177 NW 81st Street
Miami, Florida 33150

Dear Mr. Francois:

We inspected your firm at the above address, on November 13-14, 2003 and reviewed your revised Hazard Analysis Critical Control Point (HACCP) plans sent on January 15, 2004, and found that you have serious deviations from the seafood HACCP regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your fishery products are adulterated, in that your histamine-forming fish and imported fish have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." Our investigation determined that some of your histamine species are transported for more than 4 hours. However, your firm's HACCP plan for "Histamine Producing Fish" (scombroid species) fails to list a critical limit at the Receiving critical control point for fish that have been transported for more than 4 hours to control the hazard of histamine formation. FDA recommends a method of assuring that these types of products are adequately cooled throughout transportation. When these species are transported for more than 4 hours, we suggest that you either monitor the adequacy of the cooling media at receipt or obtain documentation of continuous temperature monitoring during transport.

2. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations of the adequacy of ice checks performed at the Cooler/Storage critical control point to control histamine formation listed in your HACCP plan for scombroid species.

3. Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, in your HACCP plan for scombroid species, your corrective action plan to "add ice and evaluate total time/temperature exposure during storage" at the Cooler/Storage critical control point is inadequate because it does not address the cause of the deviation, and it does not prevent adulterated product from entering the market.

4. If you obtain fish or fishery products from a country that does not have a qualifying memorandum of understanding (MOU) or similar agreement with the FDA, you must have and implement written verification procedures for ensuring that the fish or fishery products were processed in accordance with the requirements of 21 CFR Part 123. Your written verification procedures must list, at a minimum, product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications to address the hazard of histamine associated with the Mahi-Mahi you imported from Brazil.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces (21 CFR 123.11(b)) with sufficient frequency to prevent cross contamination, as evidenced by condensate dripping on the cutting table.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as new or revised HACCP plans, product specifications and completed monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari H. Shambaugh, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Shambaugh at (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District